



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 6, 2020

Heidi Popelka
Senior Regulatory Specialist II
ECOLAB, INC.
1 Ecolab Place
St. Paul, MN 55102

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: VORTEXX
EPA Registration Number: 1677-158
Application Date: March 25, 2020
Decision Number: 561527

Dear Ms. Popelka:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

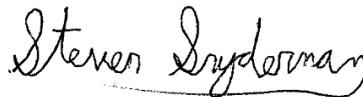
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Reovirus (ATCC VR-2040) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

VORTEXX

ACID LIQUID SANITIZER FOR FOOD PROCESSING EQUIPMENT
in Dairies, Dairy Farms, Breweries, Wineries, Beverage and Food Processing Plants

DISINFECTANT

Veterinary Clinics, Animal Life Science Laboratories, Industrial Facilities, Office Buildings, Recreational Facilities, Retail and Wholesale Establishments, Animal Care Facilities, Veterinary Facilities, Farms, Livestock Quarters, Poultry Premises, and Poultry Hatcheries

STERILANT FOR ASEPTIC MANUFACTURING AND PACKAGING EQUIPMENT

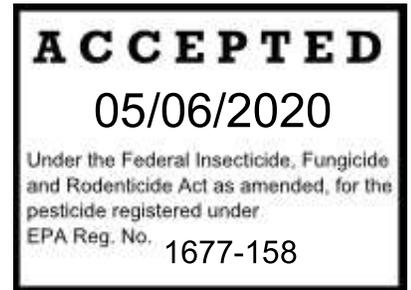
DISINFECTANT FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY

Active Ingredients:

Hydrogen Peroxide.....	6.9%
Peroxyacetic Acid.....	4.4%
Octanoic Acid	3.3%

Inert Ingredients:..... 85.4%

Total: 100.0%



KEEP OUT OF REACH OF CHILDREN DANGER

(See [back], [side], [other] label for [complete] [additional] [directions for use] [precautionary statements] [and] [first aid])

(Refer to the (MSDS)(SDS) for additional product hazard information)

PRECAUTIONARY STATEMENTS –

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. Harmful if inhaled or swallowed. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses) and protective gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 –20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

ENVIRONMENTAL HAZARDS: (containers 5 gallons or greater) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SANITIZATION

VORTEXX is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, breweries, wineries, beverage and food processing plants. This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO₃.

NOTE: FOR MECHANICAL OPERATIONS, prepared use solutions may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS, fresh sanitizing solutions must be prepared at least daily or more often if the solution becomes diluted or soiled.

SANITIZING FOOD CONTACT SURFACES

Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1 to 2 oz. **VORTEXX** per 6 gallons of water (0.13 - 0.26% v/v concentration). At this dilution **VORTEXX** is effective against *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11229), *Escherichia coli* 0157:H7 (ATCC 43895), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* (ATCC 15442), *Cronobacter sakazakii* (ATCC 12868) and *Vibrio cholerae* (ATCC 25873) as well as beverage spoilage organism *Lactobacillus malefermentans* (ATCC 11305). Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces must be exposed to the sanitizing solution for a period of not less than one minute unless a longer time is specified by the governing sanitary code. Drain thoroughly. (Do not rinse.) or (No rinse necessary.)

SANITIZING EATING, DRINKING, AND FOOD PREP UTENSILS

1. Remove gross food particles by a prescrape, preflush and, when necessary, a presoak treatment.
2. Wash with detergent.
3. Rinse with clean water.
4. Sanitize in a solution of 1 to 2 oz. **VORTEXX** per 6 gallons of water (0.13 - 0.26% v/v concentration). Immerse all utensils for at least 1 minute or contact time specified by governing sanitary code.
5. Drain and air dry.

ELEVATED TEMPERATURE SANITIZING

At a temperature of 120° F. VORTEXX can be used as a food contact sanitizer at 1 oz. per 14 gallons water (0.055% v/v concentration) up to 1 oz. per 6 gallons of water (0.13% v/v concentration). At this concentration VORTEXX is effective against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229). All surfaces must be exposed to the sanitizing solution for a period of not less than one minute, unless otherwise specified by governing sanitary code. Drain thoroughly. (Do not rinse.) or (No rinse necessary.)

SANITIZING TABLEWARE

For sanitizing tableware in low-temperature (minimum 120° F) warewashing machines, inject **VORTEXX** into the final rinse water at a concentration of 0.055% v/v (1 oz. per 14 gallons of water) up to 0.13% v/v (1 oz. per 6 gallons of water) at 120° F. Allow 1 minute contact. Air dry.

To insure that the **VORTEXX** concentration does not fall below 0.055%, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your local Ecolab Specialist for technical assistance and further information on sanitizing tableware in warewashing machines.

FINAL SANITIZING BOTTLE RINSE

VORTEXX may be used as a final sanitizing rinse for returnable and non-returnable bottles (e.g. glass or PET) at a 0.13% dilution (1 oz. to 6 gallons) up to 0.26% dilution (2 oz. to 6 gallons). At this dilution VORTEXX is effective against *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11229), *Escherichia coli 0157:H7* (ATCC 43895), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (ATCC 6539), *Pseudomonas aeruginosa* (ATCC 15442), *Cronobacter sakazakii* (ATCC 12868), *Vibrio cholerae* (ATCC 25873), and *Lactobacillus malefermentans* (ATCC 11305). All surfaces must be exposed to the sanitizing solution for a period of not less than 1 minute. Drain thoroughly. (Do not rinse) or (No rinse necessary.)

- Suitable for use in bottle rinse applications.

FINAL BOTTLE AND CLOSURE CLEANING RINSE

VORTEXX may be used as a final cleaning rinse for returnable and non-returnable bottles (e.g. glass or PET) and closures not requiring a final food contact surface sanitizing rinse when used up to 2 oz. per 6 gallons of water (up to 0.26% v/v or 2600 ppm product). Drain thoroughly. (Do not rinse) or (No rinse necessary.)

CLEANING HARD SURFACE

DIRECTIONS FOR USE AS A HARD SURFACE CLEANER

For hard surface cleaning applications, remove gross food particles, then wash using **VORTEXX** up to 2 oz. per 6 gallons of water (up to 0.26% v/v or 2600 ppm product). All hard food contact surfaces treated with this cleaning system must be drained thoroughly. (Do not rinse) or (No rinse necessary.)

CLEANING HARD SURFACE FOOD PROCESSING EQUIPMENT– NO RINSE

For hard surface cleaning applications, remove gross soil particles from surfaces, then thoroughly clean surfaces with a concentration up to 2 oz. per 6 gallons of water (up to 0.26% v/v or 2600 ppm product). Use immersion, coarse spray or circulation techniques as appropriate to clean surfaces. Allow surfaces to drain thoroughly. (Do not rinse) or (No rinse necessary.)

CLEANING HARD SURFACE PROCESSING EQUIPMENT– RINSE FOR FOOD CONTACT SURFACES

For hard surface cleaning applications, remove gross soil particles from surfaces, then thoroughly clean surfaces with a concentration up to 1.0% (5 oz. /4 gallons). All treated hard non-porous food contact surfaces must be rinsed thoroughly with a potable water rinse prior to reuse.

CONTINUOUS TREATMENT OF CONVEYORS

Wash, rinse and sanitize conveyor equipment. During processing, apply **VORTEXX** at no more than 0.13% - 0.26% v/v (1 to 2 oz. per 6 gallons of water) concentration to conveyor with Mikro Master or other suitable feeding equipment. At this dilution **VORTEXX** is effective against *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11229), *Escherichia coli* 0157:H7 (ATCC 43895), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* (ATCC 15442), *Cronobacter sakazakii* (ATCC 12868) and *Vibrio cholerae* (ATCC 25873). Controlled volumes of **VORTEXX** are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of **VORTEXX** from equipment and to prevent puddles on top of belt. During interruptions in operations, coarse spray the processing equipment with **VORTEXX** solution at not more than 0.26% v/v concentration. Conveyor equipment must be free of product when applying coarse spray. Conveyor surface must be exposed to the sanitizing solution for a period of not less than 60 seconds.

- Registered for continuous treatment of conveyors in food processing operations
- Reduces harmful microorganisms* on critical meat, poultry and fruit/vegetable conveyor surfaces during processing.

*For a list of organisms, see directions for use on product label.

SANITIZING NON-FOOD CONTACT SURFACES

Pre-clean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, drip pans with 1 oz. **VORTEXX** per 8 gallons water (0.1% v/v concentration) up to 2 oz. per 6 gallons of water (up to 0.26% v/v concentrate). At this concentration the product is effective against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), *Escherichia coli* 0157:H7 (ATCC 43895), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* (ATCC 15442) in 500 ppm hard water. The product is also effective against beverage spoilage organisms: *Aspergillus niger* (ATCC 6275), *Saccharomyces cerevisiae* (ATCC 834), *Pediococcus damnosus* (ATCC 25248) and *Lactobacillus malefermentans* (ATCC 11305). All surfaces must be exposed to the sanitizing solution for a period of not less than 5 minutes. Drain thoroughly and allow to air dry. (Do not rinse) or (No rinse necessary.)

- Effective against spoilage microorganisms* that can adversely affect product quality.
- *For a list of organisms, see directions for use on product label.

SANITIZING HARD, NON-POROUS, NON-EDIBLE OUTSIDE SURFACES OF AIRTIGHT, SEALED PACKAGES CONTAINING FOOD OR NON-FOOD PRODUCTS

VORTEXX may be used as a final sanitizing rinse for hard, non-porous non-edible outside surfaces of airtight, sealed packages containing food or non-food products at a 0.13% - 0.26% v/v dilution (1 to 2 oz. per 6 gallons of water). The treated hard, non-porous, non-edible packaging, such as food wraps and meat casings, must be removed and discarded before packaged food products are further processed or consumed. All surfaces must be exposed to the sanitizing solution for a period of not less than 1 minute. Drain thoroughly. (Do not rinse) or (No rinse necessary.) This is not to be used on porous surfaces.

FOAM SANITIZING NON-FOOD CONTACT SURFACES (This use not approved in the state of California)

VORTEXX is an effective foam sanitizer of pre-cleaned non-food contact surfaces, such as boots, floors, walls, and drains, and equipment surfaces. For this application, prepare a solution of 0.13% v/v (1 oz. per 6 gallons water) **VORTEXX** and 0.13% v/v (1 oz. per 6 gallons water) **Liquid K**. For example, in 6 gallons of water, add 1 ounce of **VORTEXX** and 1 ounce of **Liquid K**. Apply solution as a foam using recommended equipment. Wet surfaces thoroughly. At this concentration, the product is effective against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), and *Listeria monocytogenes* (ATCC 49594). Surfaces must be exposed to the sanitizing foam for a period of not less than 5 minutes. No rinse is necessary. Contact your Ecolab representative for information on Liquid K or EcoCare 600 FA foaming agents and a recommended foam generation device.

- Can be used for CIP, spray, and soak sanitizing applications. Can be used in foam sanitizing applications with approved additive Liquid K™

SANITIZING NON-FOOD CONTACT PACKAGING EQUIPMENT

Prior to use of this product, remove gross soil particles from surfaces. Wash with a recommended detergent solution, rinse thoroughly with potable water. For sanitization against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), *Escherichia coli* 0157:H7 (ATCC 43895), *Listeria monocytogenes* (ATCC 49594), *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* (ATCC 15442) as well as beverage spoilage organisms, *Aspergillus niger* (ATCC 6275), *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305) and *Saccharomyces cerevisiae* (ATCC 834), apply 0.1 - 0.5% (1 to 5 oz. per 8 gallons of water) of **VORTEXX** to surfaces at a temperature of 25° to 45°C and allow to remain wet for at least 5 minutes. Allow surfaces to drain thoroughly before operations are resumed. Drainage may be followed by a potable or sterile water rinse.

- Effective against spoilage microorganisms* that can adversely affect product quality.
*For a list of organisms, see directions for use on product label.

SANITIZE PRE-CLEANED OR NEW RETURNABLE OR NON-RETURNABLE BOTTLED WATER CONTAINERS

To sanitize pre-cleaned or new returnable or non-returnable containers for bottled water processing, apply **VORTEXX** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) at a temperature of 40° to 60° C for at least 7 seconds. At these conditions, **VORTEXX** is effective against *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11229), *Salmonella typhi* (ATCC 6539), *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305), *Saccharomyces cerevisiae* (ATCC 834) and *Aspergillus niger* (ATCC 6275). After thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

ANTIMICROBIAL RINSE OF PRE-CLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305), *Saccharomyces cerevisiae* (ATCC 834) and *Aspergillus niger* (ATCC 6275), apply **VORTEXX** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) at a temperature of 40° to 60° C for at least 7 seconds. After thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305), *Saccharomyces cerevisiae* (ATCC 834) and *Penicillium digitatum* (ATCC 36038), apply **VORTEXX** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) at a temperature of 15° to 60° C for at least 15 seconds. After

thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

- Effective against spoilage microorganisms* that can adversely affect product quality.
*For a list of organisms, see directions for use on product label.

ANTIMICROBIAL RINSE OF PRE-CLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS WITH THE ADDITION OF SURFACTANT

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus* (ATCC 25248), *Lactobacillus malefermentans* (ATCC 11305), *Saccharomyces cerevisiae* (ATCC 834), and *Aspergillus niger* (ATCC 6275), apply **VORTEXX** as follows. Add 6.7 oz. of surfactant product to 10 gallons of prepared **VORTEXX** solution. Prepare **VORTEXX** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) solution. Use one of the following surfactants, KX-7014, KX-7015, KX-7016, or KX-7017. Apply at a temperature of 40° to 60° C with a contact time of at least 7 seconds. After thorough draining, rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

- Effective against spoilage microorganisms* that can adversely affect product quality.
*For a list of organisms, see directions for use on product label.

ANTIMICROBIAL RINSE FOR PRE-CLEANED FOOD-CONTACT SURFACES

Prior to antimicrobial rinsing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. To reduce the number of food spoilage non-public health microorganisms *Bacillus coagulans*, *Bacillus sporothermodurans*, *Clostridium butyricum*, *Alicyclobacillus acidoterrestris* and *Geobacillus stearothermophilus*, apply **VORTEXX** at a concentration of 1 to 2 ounces per 6 gallons of water (0.13 – 0.26% v/v concentration) at a temperature of 120 to 160 °F for at least 5 minutes. Drain thoroughly. (Do not rinse.) or (No rinse necessary.)

- Effective against spoilage microorganisms* that can adversely affect product quality.
*For a list of organisms, see directions for use on product label.

BACTERIOPHAGE CONTROL

When applied to pre-cleaned surfaces, **VORTEXX** will reduce the incidence of *Lactococcus lactis* subsp. *Lactis*, *lactococcus lactis* subsp. *Cremonis*, and *Streptococcus thermophilus* bacteriophage in cheese manufacturing establishments by spraying or immersion of equipment at concentrations of 1-2 oz. per 6 gallons (0.13 - 0.26% v/v concentration) of water. All surfaces must be exposed to the solution for a period of not less than one minute. Drain thoroughly. (Do not rinse.) or (No rinse necessary.)

DISINFECTION

VORTEXX disinfects as it cleans in one operation. **VORTEXX** can be used to disinfect floors, walls and other hard, non-porous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

Areas of Use: Use **VORTEXX** in veterinary clinics, animal life science laboratories, industrial facilities, office buildings, recreational facilities, retail and wholesale establishments.

Combination Disinfection and Cleaning

VORTEXX is effective against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica*

(ATCC 10708) at 0.2% - 1.0% (1 oz. /4 gallons to 5 oz. /4 gallons) in hard water (500 ppm as CaCO₃) and 5% blood serum on hard non-porous surfaces.

For heavily soiled areas a pre-cleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted. Rinse food contact surfaces that come in contact with food with potable water prior to reuse.

Virucidal*

At 0.2% (1 oz./4 gals.) up to 1.0% (5 oz. /4 gallons) **VORTEXX** is effective against Influenza B (ATCC VR-296), Influenza A(H3N2) (ATCC VR-544), Influenza A (H1N1) (ATCC VR-897), Influenza A (H10N7) (ATCC VR-1334), Avian Influenza A (H3N2) (ATCC VR-2072) and Reovirus (ATCC VR-2040) on hard inanimate surfaces when used at 20° C with a 10 minute contact time in the presence of 500 ppm hard water and organic soil. Apply as directed under disinfection.

- Effective against Avian Influenza A (H3N2) virus as listed on the product label.

Fungicidal

VORTEXX can be used on hard non-porous inanimate surfaces such as shower room floors, locker room benches, shower stalls and bath mats. At 0.2% (1 oz./4 gallons) up to 1.0% (5 oz. /4 gallons) the product is effective against *Trichophyton mentagrophytes* (Athletes Foot Fungi) (ATCC 9533) and *Candida albicans* (pathogenic yeast) (ATCC 18804) in the presence of protein (5% blood serum) in 500 ppm hard water with a 10 minute contact time. Apply as directed under disinfection.

STERILIZATION OF CLOSED SYSTEM MANUFACTURING, FILLING, AND PACKAGING EQUIPMENT IN ASEPTIC PROCESSES

Prior to use of this product, remove gross soil particles from processing surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a 5-6% sterilizing solution of **VORTEXX**. Circulate, coarse spray, or flood the sterilizing solution as appropriate to the equipment. All surfaces must be exposed to the sterilizing solution for 30 minutes. This product is effective against *Clostridium sporogenes* (ATCC 3584) and *Bacillus subtilis* (ATCC 19659) at 5-6% (25-30 oz./4 gallons) in 100 ppm hard water and 5% organic load at 20° C. Thoroughly rinse food contact surfaces with either a sterile water or potable water rinse. This product is not for use as a sterilant on medical devices.

DISINFECTING PHARMACEUTICAL AND COSMETIC SURFACES

VORTEXX is recommended for use on hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities. **VORTEXX** is effective against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) at 0.2% (1 oz./4 gallons) up to 1.0% (5 oz. /4 gallons) in hard water (500 ppm as CaCO₃) and 5% blood serum. For heavily soiled areas a-pre-cleaning step is required. Rinse all surfaces thoroughly with the disinfecting solution and maintain a contact time of at least 10 minutes. Product contact surfaces must be rinsed with sterile water.

POULTRY HOUSE DISINFECTION

VORTEXX is effective against the Avian Influenza A (H3N2) (ATCC VR-2072) virus.

Special Instructions for Inactivating Avian Influenza A.

1. Remove all poultry and feeds from premises, trucks, coops, and crates.

2. Remove all litter and droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry
 3. Empty all troughs, racks, and other feeding and watering appliances.
 4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
 5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
 6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
 7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap and detergent, and rinse with potable water before reuse.
- Effective against Avian Influenza A (H3N2) virus as listed on the product label.

FARM PREMISE DISINFECTION

VORTEXX is effective against the Avian Influenza A (H3N2) (ATCC VR-2072) virus.

Special Instructions for Inactivating Avian Influenza A.

1. Remove all animals and feed from premises, vehicles, and enclosures.
 2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
 3. Empty all troughs, racks, and other feeding and watering appliances.
 4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
 5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
 6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
 7. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipments until treatment has been absorbed, set, or dried.
 8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap and detergent and rinse with potable water before reuse.
- Effective against Avian Influenza A (H3N2) virus as listed on the product label.

NOTE: This product in its use solutions is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

Vortexx (chemical) (concentration) can be monitored real-time, decreasing dependence on manual titrations. See separate instructions for using (add equipment name) monitoring equipment.

- Enables reduced water consumption for CIP rinse (for CIP programs with a rinse post-sanitizer)
- Allows for automatic monitoring of the entire CIP process
- Improves continuous control of sanitizer concentrations in recirculation systems
- Improves concentration control in ESL and antimicrobial bottle rinse applications
- (Saves time because) Chemical concentration can be monitored real-time decreasing dependence on manual titrations. See separate instructions for using (add equipment name) monitoring equipment.

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Product must be kept cool and in a vented container to avoid any explosion hazard.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING AND DISPOSAL:

(2.5 gal bladder in box) Nonrefillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer box and bladder for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers >5-55 gallons.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(Totes) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

STRONG OXIDIZING AGENT

EPA Reg. No. 1677-158

EPA Est. 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2(R), 1677-TX-1(D),
1677-IL-2(J), 1677-GA-1(M), 1677-CA-1(S), 1677-WV-1(V)

Superscript refers to first letter of date code

Ecolab Inc.
370 Wabasha Street No.
St. Paul, MN 55102

(Made in the United States of America)
(Made in USA)
U.S. Patent No. 5200189 and 5314687
Other Patents Pending

Net Contents:	1 U.S. Gallon (3.78 L)
	4 U.S. Gallons (15.1 L)
	2.5 U.S. Gallons (9.45 L)
	15 U.S. Gallons (56.8 L)
	30 U.S. Gallons (113.5 L)
	50 U.S. Gallons (189 L)
	300 U.S. Gallons (tote)

Optional marketing language:

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.
- This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

- Enhances (Promotes Quality Assurance) finished product quality when used in a total Ecolab product and professional services program, by reducing pathogenic organisms*.
*For a list of organisms, see directions for use on product label.
- Helps protect processing equipment investment - use solutions noncorrosive to 304, 316, and 410 stainless steel surfaces when used at recommended concentrations.
- Compatible with most plastic and rubber materials used in processing operations.
- Low foaming formulation minimizes CIP cycle time and improves operating efficiency.
- Sheeting action results in spotless equipment, patented surfactant formulation provides better wetting and rinsing.
- Active ingredients rapidly break down after use into water, oxygen, acetic acid, and octanoic acid.
- Low phosphorus formulation minimizes phosphate-related effluent fees.
- Product contains no iodine, chlorine, or quats.

Emerging Viral Pathogens

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.”

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses

<i>For an emerging viral pathogen that is an...</i>	<i>...follow the directions for use for the following organisms on the label</i>
Enveloped virus	Reovirus (ATCC VR-2040)

Acceptable claim language:

Vortexx has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, Vortexx can be used against [name of emerging virus] when used in accordance with the directions for use against Reovirus (ATCC VR-2040) on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus.] Vortexx kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Reovirus (ATCC VR-2040) on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.